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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/991,247	11/15/2001	Gary K. Michelson	101.0083-00000	4911

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EXAMINER

PREBILIC, PAUL B

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 08/13/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

EC

Office Action Summary

Application No.

09/991,247

Applicant(s)

MICHELSON, GARY K.

Examiner

Paul B. Prebilit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**P r i d f r Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 5-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 5-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 November 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7. 6) ☐ Other:

Specification

The disclosure is objected to because of the following informalities:

On page 20, lines 1 and 15-18, the patent application numbers may not be updated with the current status. If these applications are now patented, the patent numbers should be indicated in the same sentence of paragraph.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 17 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 17 is not enabled because the specification fails to enable one to make and/or use the claimed invention without undue experimentation. This is because no examples of compounds which perform this function have been set forth.

As an alternative to the lack of enablement rejection above, claim 17 can be viewed as lacking an adequate written description as set forth below.

Claim 17 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which

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was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 17 is not adequately supported from the specification because the specification fails to adequately describe or disclose what constitutes a scar inhibiting material as claimed. For example, it is not clear whether any emollient would fall within the claim scope or whether the language is limited to some specific set of drugs that act on the nucleus of the bone cells.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 19-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The scope of claims' 19-22 body includes insertion devices and tools which are not part of an implant. Since the preamble of base claim 1 is to an implant, the preamble does not encompass these additional elements. For this reason, there is an inconsistency between the scope of the preamble and the body of each claim. For this reason, these claims are considered to be indefinite because it is unclear what is being positively claimed.

With regard to claims 20 and 21, the preamble does not agree with that of their base claim 1, and thus, it is unclear how interpret these claims.

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 5-13, 18, 19, and 22 are rejected under 35 U.S.C. 102(e) as anticipated by Boyle et al (US 6,277,149) or, in the alternative, under 35 U.S.C. 103(a) as obvious over Boyle et al (US 6,277,149) in view of Boyce et al (US 6,294,187).

Regarding claims 1-3, 5-13, 18, 19, and 22, Boyle discloses a body (Figures 16-19) that can be inserted into a disc space as claimed. The upper and lower surfaces of Boyle's device are arcuate as claimed; see Figures 16-19. An opening (26) passes through the upper and lower surfaces as claimed; see Figure 1 and column 4, lines 4-13. Furthermore, Boyle's implant can be made of a composite of cortical bone and bioresorbable material because Boyce is incorporated into Boyle's disclosure; see column 4, lines 29-34 and see Boyce on column 2, line 46 to column 3, line 7, column 4,

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lines 26-63; column 7, line 55 to column 8, line 39 and column 11, line 65 to column 12, line 9. For these reasons, the claim language is considered to be fully met by Boyle.

Alternatively, one could interpret Boyle as not fully meeting the claim language because it does not explicitly specify a combination of cortical bone particles and bioresorbable material can be used. With this interpretation, the Examiner asserts that the claim language is at least prima facie obvious in view of Boyce which discloses that the claimed combination was known.

With regard to claim 19 specifically, Applicant is directed to Figure 20 where a hollow portion is shown on the right end of insertion device such that the claim language is met.

Claims 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boyle et al and Boyce et al as applied to claim 1-3, 5-13, 18, 19, and 22 above, and further in view of Michelson (US 5,860,973). Boyle discloses inserting a fusion inducing material into the opening but fails to disclose putting this material on the upper and lower surfaces as claimed. However, Michelson teaches that it was known to coat similar vertebral implants with a fusion promoting material; see column 5, line 57 to column 6, line 5. Therefore, it would have been obvious to coat the implant of Boyle with fusion promoting material in order to better promote fusion which is the same reason that Michelson does the same.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Boyle et al and Boyce et al as applied to claims 1-3, 5-13, 18, 19, and 22 above, and further in view of Boyce et al (US 5,899,939). Boyle fails to disclose the use of a scar inhibiting

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material with the implant as claimed. However, Boyce ('939) discloses that it was known to coat many types of medically/surgically useful substances onto similar vertebral implants; see column 4, line 53 to column 5, line 32. Therefore, it is the Examiner's position that it would have been obvious to coat the Boyle device with any useful substance, including scar-inhibiting materials, since there has been no showing of criticality for using such a substance in the same environment as Boyle and Boyce.

Claims 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boyle et al and Boyce et al as applied to claims 1-3, 5-13, 18, 19, and 22 above, and further in view of Michelson (US 5,484,437). Boyle fails to disclose the use of a drill, mill, and hollow tube capable of passing a bone removal device therethrough as claimed. However, Michelson teaches that the use of a hollow insertion tube, drill, and mill were known at the time the invention was made; see Figure 11A and column 21, line 54 to column 22, line 22. Therefore, it is the Examiner's position that it would have been obvious to include a hollow insertion tube, drill, and mill with the Boyle implant in order to prepare an implantation site for the implant of Boyle as taught by Michelson.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

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Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Prebilic whose telephone number is (703) 308-2905. The examiner can normally be reached on Monday-Thursday from 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on (703) 308-2111. The fax phone number for this Technology Center is (703) 872-9302.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 3700 receptionist whose telephone number is (703) 308-0858.



Paul Prebilic
Primary Examiner
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